

EMA recommends COVID-19 Vaccine Janssen for authorisation in the EU

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Janssen vaccine is the only single-dose vaccine under recommendation at present



EMA has recommended granting [conditional marketing authorization](#) for COVID-19 Vaccine Janssen to prevent COVID-19 in people from 18 years of age.

After a thorough evaluation, EMA's human medicines committee ([CHMP](#)) concluded by consensus that the data on the vaccine were robust and met the criteria for [efficacy](#), safety and quality. COVID-19 Vaccine Janssen is the fourth vaccine recommended in the EU for preventing COVID-19.

The safety and effectiveness of the vaccine will continue to be monitored as it is used across the EU, through the EU [pharmacovigilance](#) system and additional studies by the company and European authorities.

COVID-19 Vaccine Janssen is an adenovirus vaccine that has been modified to contain the gene for making the SARS-CoV-2 spike protein. This is a protein on the SARS-CoV-2 virus which it needs to enter the body's cells.

The European Commission will now fast-track the decision-making process to grant a decision on the conditional marketing authorisation for COVID-19 Vaccine Janssen, allowing vaccination programmes to be rolled out across the EU. Conditional marketing authorisation (CMA) is used as the fast-track authorisation procedure to speed up approval of treatments and vaccines during public health emergencies in the EU.

Monitoring the safety of COVID-19 Vaccine Janssen

During the assessment of COVID-19 Vaccine Janssen, the CHMP had the support of EMA's safety committee, PRAC, who assessed the risk management plan of COVID-19 Vaccine Janssen, and the COVID-19 EMA pandemic task force (COVID-ETF), a group that brings together experts from across the European medicines regulatory network to facilitate rapid and coordinated regulatory action on medicines and vaccines for COVID-19.